

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparative study of the effect of caffeine and doxapram on respiratory parameters of patients admitted to intensive care units after spinal surgery

Protocol summary

Study aim

Determining and comparing the effect of caffeine and doxapram on respiratory parameters of patients admitted to intensive care units after spinal surgery

Design

A randomized, double-blinding clinical trial, with the parallel groups, Phase 3 on 96 patients

Settings and conduct

In this randomized double-blind clinical trial study, 96 eligible patients undergoing spinal surgery admitted to the intensive care unit of Al-Zahra Hospital in Isfahan will be included in the study and will be randomly divided into three groups. Patients in the first group will be prescribed doxapram, in the second group "caffeine citrate", and in the third group "normal saline", then their hemodynamic parameters will be compared between the three groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria include the age group of 18-70 years, has a class 1 and 2 classification of the American Society of Anesthesiologists (ASA), a candidate for spine surgery and consent to participate in the study. Exclusion criteria are confirmed cerebral edema, sensitivity to the studied drugs, having hemoglobin less than 9 g/dl and having a history of underlying diseases (such as cardiovascular disease, lung disease, hypertension, hyperthyroidism).

Intervention groups

Intervention group 1: Patients in this group will be infused with doxapram 5 mg / kg for three hours.
Intervention group 2: Patients in this group will be infused with caffeine citrate 5 mg / kg for three hours.
Control group: Patients in this group will be infused with 250 cc of normal saline (as a placebo) for three hours.

Main outcome variables

Respiratory Rate; oxygen saturation (SPO2); Blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200825048515N51**

Registration date: **2022-02-03, 1400/11/14**

Registration timing: **prospective**

Last update: **2022-02-03, 1400/11/14**

Update count: **0**

Registration date

2022-02-03, 1400/11/14

Registrant information

Name

Asieh Maghami Mehr

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 0000 0000

Email address

asimaghami@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-04, 1400/11/15

Expected recruitment end date

2022-04-20, 1401/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the effect of caffeine and doxapram on respiratory parameters of patients admitted to intensive care units after spinal surgery

Public title

Comparison of the effect of caffeine and doxapram on respiratory parameters of patients after spinal surgery

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age category 70-18 years Class I and II classification of the American Society of Anesthesiologists(ASA)
Candidate for spine surgery Satisfaction to participate in the study

Exclusion criteria:

Existence of confirmed cerebral edema Sensitivity to the studied drugs Having hemoglobin less than 9 g/dL
Having a history of underlying diseases (such as cardiovascular disease, lung disease, hypertension, hyperthyroidism)

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 96 eligible patients are randomly selected. For this, the letter A is written on 32 sheets, the letter B is written on 32 sheets, and the letter C is written on 32 sheets and each of them is placed in an envelope. Each patient is then asked to choose one of the envelopes. Depending on the selected envelope, the patient is assigned to one of three groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, two drugs, doxapram, caffeine and placebo, are pre-prepared by the pharmacist in the same shape and color and placed in coded packages and delivered daily to the researcher, who is unaware of the type of each. Medications are prescribed. Also, the person recording the clinical and basic information of the patients as well as the statistical analyst will not be aware of the type of intervention.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Isfahan University of Medical Sciences

Street address

Street address Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq

City

Isfahan

Province

Isfahan

Postal code

8179964167

Approval date

2020-01-09, 1398/10/19

Ethics committee reference number

IR.MUI.MED.REC.1398.514

Health conditions studied**1****Description of health condition studied**

Spinal surgery

ICD-10 code

M43.20

ICD-10 code description

Fusion of spine, site unspecified

Primary outcomes**1****Description**

Respiratory Rate

Timepoint

Half an hour before entering the intensive care unit and at 6, 12, 18, 24, 30, 36, 42, 48 hours after intervention

Method of measurement

Ventilator device

2**Description**

Oxygen saturation(SPO2)

Timepoint

Half an hour before entering the intensive care unit and at 6, 12, 18, 24, 30, 36, 42, 48 hours after intervention

Method of measurement

Ventilator device

3

Description

Blood pressure

Timepoint

Half an hour before entering the intensive care unit and at 6, 12, 18, 24, 30, 36, 42, 48 hours after intervention

Method of measurement

Ventilator device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Patients in this group will be infused with doxapram (Behbod Daroo Company) 1 mg / kg for three hours.

Category

Treatment - Drugs

2

Description

Intervention group 2: Patients in this group will be infused with caffeine citrate (Chemidarou Company) 5 mg / kg for three hours.

Category

Treatment - Drugs

3

Description

Control group: Patients in this group will be infused with 250 cc of normal saline as a placebo (Darou Pakhsh Company) for three hours.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

Babak Alikiaii

Street address

Soffe Blvd, Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2020

Fax

Email

alikiaib@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mansour Siavash Dastjerdi

Street address

Vice Chancellor for Research, School of Medicine, Hezar Jarib Street, Isfahan.

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 8597

Email

dean@med.mui.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Isfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Babak Alikiaii

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Department of Anesthesiology; Al-Zahra Hospital; Sofeh boulevard

City

Isfahan

Province
Isfahan
Postal code
8174675731
Phone
+98 31 3620 2020
Email
alikiaib@med.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Babak Alikiaii
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Department of Anesthesiology; Al-Zahra Hospital;
Sofeh boulevard
City
Isfahan
Province
Isfahan
Postal code
8174675731
Phone
+98 31 3620 2020
Email
alikiaib@med.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Abadan University of Medical Sciences
Full name of responsible person
Mohammadhasan Houshmandi
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Department of Anesthesiology; Al-Zahra Hospital;
Sofeh boulevard
City
Isfahan
Province
Isfahan
Postal code
8174675731
Phone
+98 31 3620 2020
Email
mhhoushmandi@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available